This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 21!

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 16-R-0029
CUSTOMER NUMBER: 55

FORM APPROVED
OMB NO. 0579-0036

ANNUAL REPORT OF RESEARCH FACILITY

(TYPE OR PRINT)

Boehringer Ingelheim Pharmaceuticals Inc
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877

NOV 18 2005

Telephone: (b)(6), (b)(7)c

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary)

(b)(2)High, (b)(7)f

FACILITY LOCATIONS (Sites) - See Atached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY **(Attach additional sheets if necessary or use APHIS Form 7023A)**

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not ye used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use o pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals an for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for wh the use of appropriate anesthetic, analgesic, or tranquiliz drugs would have adversely affected the procedures, res or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reasc such drugs were not used must be attached to this report	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs	47	59	19	55	133
5. Cats	0	0	0	0	0
6. Guinea Pigs	0	87	4	149	240
7. Hamsters					
8. Rabbits					
9. Non-human Primates	135	72	37	46	155
10. Sheep					
11. Pigs					
12. Other Farm Animals					
13. Other Animals					

ASSURANCE STATEMENTS

1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anestetic, analgesic, and tranquilizing drugs, prior to, during, and following actual rese teaching, testing, surgery, or experimentation were followed by this research facility.

2) Each principal investigator has considered alternatives to painful procedures.

3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and ap Institutional Animal Care and Use Committee (IACUC). **A summary of all such exceptions is attached to this annual report.** In addition to identifying the IACUC-approved exceptions, this summary inc brief explanation of the exceptions, as well as the species and number of animals affected.

4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL
(Chief Executive Officer or Legally Responsible Institutional Official)

(B)(6) (B)(7)(c)

DATE SIGNED 11/16/05

APHIS FORM 7023 (AUG 91)

(Replaces VS FORM 18-23 (OCT 88), which is obsolete.)

E4

49 dogs assigned to column E of this report were included (b)(4) (b)(4) in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) a limited number of animals must be exposed to test compound (b)(4). Clinical signs produced by some test compounds (b)(4) may be distressful or painful to the animal, if only transiently. To intercede prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.

6 dogs assigned to column E of this report were included (b)(4) required in the drug development process to determine a (b)(4) for the compound to be used in clinical trial studies. After being orally dosed with some test formulations, the six dogs (b)(4) 24 to 72 hours in duration. The dogs were not treated except for providing supportive therapy. Because such studies need to be conducted under as physiologically normal conditions as possible, administering relief drug therapy such as antipyretic analgesics during the syndrome may have further interfered with (b)(4) of the test article.

E6

66 guinea pigs assigned to Column E of this report were included (b)(4) (b)(4) in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) positive control animals must be (b)(4) resulting in a (b)(4), which may be distressful or painful to the animals albeit for a strictly limited period. To intercede prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.

83 guinea pigs assigned to Column E of this report were (b)(4) (b)(4) in which, to meet Food and Drug Administration requirements under Good Laboratory Practice regulations (21 CFR 58.120, 43 CFR 60013) a limited number of animals must be exposed to test compound (b)(4). Clinical signs produced by some test compounds (b)(4) may be distressful or painful to the animal. To intercede prematurely would invalidate the procedure, requiring its repetition and the consequent use of more animals.

E9

2 cynomologus monkeys assigned to Column E of this report were used to evaluate the (b)(4) of novel compounds. Preceding the administration of the novel compounds, the animals were injected parenterally with compounds intended to produce (b)(4) associated (b)(4). Although doses of the compound were titrated to produce the minimum (b)(4), these two animals experienced (b)(4) prior to receiving the novel test compound, requiring institution of support therapy including supplemental heat and intravenous steroids. The animals made a full recovery within 24 hours following onset of clinical signs and provision of supportive therapy.

4 squirrel monkeys assigned to Column E of this report were used as a model of (b)(4) in which they were sensitized by antigen in adjuvant vehicle appropriate to the route, dosed with test compound by oral route and then (b) (4) (b)(4). Although (b)(4) was minimized, systemic reactions included (b)(4). Over the course of two weeks post administration of agents, the inappetence resulted in a gradual loss of 10 percent or more of body weight. Nutritional supplements were provided and the animals returned to pretest body weight within 7 to 10 days.

40 rhesus monkeys assigned to Column E of this report were included in (b)(4) in which, to meet Food and Drug Administration requirements under Good Laboratory Practices regulations (21 CFR 58.120, 43 CFR 60013) a limited number of animals must be exposed to test compounds (b)(4) Clinical signs produced by some test compounds at (b) (4) may be distressful or painful to the animals, if only transient. To intercede prematurely would invalidate the procedure under the cited regulations, requiring repetition of the study and the consequent use of more animals.

DEC 22 2005

Boehringer Ingelheim

Boehringer Ingelheim
Pharmaceuticals Inc.

Elizabeth Goldentyer, D.V.M.
Regional Director - Animal Care
United States Department of Agriculture
Animal and Plant Health Inspection Service
Eastern Region Office
900 Main Campus Drive, Suite 200
Raleigh, NC 27606-5213

December 20, 2005

(b)(6)(b)(7)(c)

900 Ridgebury Rd/P.O. Box 368
Ridgefield, CT 06877-0368
Telephone (203) 798-9988

RE: Addendum to 2005 Annual Report, Certificate Number 16-R-0029

Dear Dr. Goldentyer:

This letter is submitted as an addendum to the 2005 Annual Report of Research Facility, Certificate Number 16-R-0029 (Attachment 1) in response to the letter from your office, dated December 12, 2005 (Attachment 2).

The federal regulations cited in support of animals reported in Column E of the report, as required by 9 CFR 2.36 (b) (7), contained an error. The correct citation is 21 CFR 58.120 and 43 FR 60013. The 43 FR 60013 component of this citation refers to the 1978 Federal Registry announcement that was the original source of 21 CFR 58.

Compliance with 21 CFR 58 is intended to assure the quality and integrity of safety data submitted in support of applications for research or marketing permit for pharmaceuticals regulated by the Food Drug Administration and required by the Federal Food, Drug, and Cosmetic Act and sections 351 and 354-360F of the Public Health Service Act.

The animals reported under Category E in our annual report for which the above citation was provided in support of their use in nonclinical laboratory studies, are defined in 21 CFR 58.3 (i) as test systems. In accordance with 21 CFR 58.3(d) "Nonclinical laboratory study means in vivo or in vitro experiments in which test articles are studied prospectively in test systems under laboratory conditions to determine their safety." In compliance with those regulations, test articles must be administered at sufficiently high dose levels to determine what the highest dose that can be administered safely to the test system without eliciting (b)(4). In order to determine the highest safe dose level, it is necessary to determine (b)(4) in the test system. (b)(4)

Boehringer Ingelheim

are determined not only by clinical signs but also by histological changes that may occur as the result of administration of the test article to the test system. Because the use of other drugs such as anti-inflammatory agents or analgesics might cause reversal of the histological (b)(4) of the test articles or induce their own inherent (b)(4) or drug-drug interactions , they could not be administered to the following test systems included in the explanations for Column E entries: 49 dogs, 149 guinea pigs and 40 rhesus monkeys. As a result, animals that experienced more than momentary pain or distress as a side effect of the test article administration were provided either supportive fluid therapy, nutritional supplements or were euthanized when their physiological condition exceeded IACUC approved humane endpoints. The remaining 6 dogs, 2 cynomolgous monkeys, 4 squirrel monkeys included in the Column E entries were provided supportive therapy as described in the original attachments to our 2005 Annual Report of Research Facility.

Thank you for this opportunity to update and clarify our 2005 Annual Report of Research Facility, Certificate Number 16-R-0029.

Respectfully,

(b)(6) (b)(7)(c)

Attachments - 2

This letter contains confidential information and must be withheld from production under the Freedom of Information Act pursuant to FOI Exemptions 3 and 4.